

**REMARKS**

Claims 1-62, 64-65, 94-100 and claims 112 are canceled without prejudice or disclaimer. Claims 63, 66-84, 89-90, 100, 102-111 have been amended. Claims 63, 66-93 and 101-111 remain currently pending in the present application.

Claim 63 has been amended to recite that the lysis step involves contacting the biological material that contains DNA with a solid support having dried thereon a lysing reagent and a RNA digesting enzyme, wherein the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer. and optionally a chelating agent. Support for this amendment can be found in the original specification and claims, such as on page 22, lines 20-21 as well as on page 21 and in claims 37-42 as originally filed. Claim 63 has also been amended to recite that the lysis step consists of contacting the biological material that contains DNA with a solid support treated with a lysing reagent and a RNA digesting enzyme. Support for this claim amendment can be found, for example, on page 13, lines 24-25. Claim 63 has also been amended to recite the optional step of treating the biological material and/or cell with at least one of a red blood cell lysing reagent, a cell suspension agent, a lytic enzyme reagent, or a protein digesting agent. Support for this amendment can be found throughout the specification, for example, on page 11, lines 21-29.

Claim 68 has been amended to recite that the eluting reagent has a pH of at least 10.0. Support for this amendment can be found throughout the specification, for example, on page 10, line 1 thereof.

Claim 110 has been amended accordingly to correct 140-150nM to recite 140-150 mM. Support for this language can be found, for example, on page 16, line 27 of the specification. Claims 110 and 111 are now written in independent form. Various of the other pending claims were amended in formal regards, such as to correct dependencies.

Accordingly, since all of the claim amendments have support in the specification, applicants submit that the present claim amendments do not add any new matter.

### **New Matter Rejections**

The Examiner rejected the claims for containing the language “but lacks a chaotropic agent” as allegedly adding new matter. The claims have been amended to remove this language, and instead, the lysing agent is now recited as what it contains as opposed to using a negative limitation. Applicants do not agree with this rejection but have introduced the instant claim amendment solely in an effort to expedite prosecution of this application.

The examiner also rejected claim 68 for the language “of at least about 10.5” as allegedly containing new matter. Claim 68 has been amended to recite a pH of at least about 10.0.

The examiner rejected claim 110 for reciting 140-150 nM ammonium chloride as new matter as the specification recites mM. Claim 110 has been amended accordingly to replace “nM” with “mM.”

Applicants assert that these claim amendments render these rejections moot, and accordingly, applicants request withdrawal of these rejections.

### **Claim rejections 35 U.S.C. § 112**

The examiner has rejected claim 68 for the phrase “at least about.” The claim has been amended to remove the term “about” rendering this ground of rejection moot. Accordingly, applicants request withdrawal of this rejection.

### **Claim rejections 35 U.S.C. § 103**

Rejection of claim 112 under 35 U.S.C. 103(a) as being unpatentable over Harvey in view of Rudi as evidenced by Ahmed and the rejection of claim 112 under 35 U.S.C. 103(a) as being unpatentable over Boom in view of Shieh and in view of Rudi.

Applicants submit that the rejections of claim 112 have been rendered moot with its cancellation, and accordingly applicants request withdrawal of this ground of rejection.

Rejection of 63-67, 69-90, 101-109 and 112 under 35 U.S.C. § 103 as being unpatentable over Deggerdal in view of Shieh or Harvey, and in view of Rudi.

It is believed the present claim amendments render this ground of rejection moot. Claim 63 and claims dependent thereon, as well as claims 110 and 111 recite a step of lysing a cell by a step consisting of contacting the biological material that contains DNA with a solid support having dried thereon a lysing reagent and a RNA digesting enzyme, wherein the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer, and optionally a chelating agent.

It is respectfully submitted that Deggerdal does not teach or suggest contacting the biological material that contains DNA with a solid support having dried thereon a lysing reagent and a RNA digesting enzyme.

Neither Shieh, Harvey nor Rudi provide for the deficiencies of Deggerdal. Shieh does not teach or suggest a pretreated support having an RNA digesting enzyme and a lysing agent dried thereto. Further, Shieh does not even relate to isolating nucleic acids at all, but rather, relates to isolating proteins from blood and plasma. Harvey only teaches the use of a lysing agent and does not teach or suggest the addition of an RNA digesting enzyme. Further, the lysing agent in Harvey is a chaotropic salt, whereas the present invention requires that the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer, and optionally a chelating agent. Thus, Harvey not only fails to teach a support having a lysing reagent and an RNA digesting enzyme dried on the support, it also fails to teach the lysing reagent claimed in the present claims. Rudi also fails to teach or suggest that the lysing reagent and an RNA digesting enzyme are added to the support and dried before addition of the biological material. In Rudi, the RNA digesting enzyme is added in solution phase and thus is not dried to the support before the addition of the biological material.

Having the lysing reagent and the RNA digesting enzyme dried on the support provides for a longer storage time. It is known in the art that over time, the detergent could inactivate the RNA digesting enzyme if maintained in solution. By having both of these agents dried on the support together, their activity can be maintained over long term storage, and yet surprisingly, they are both immediately available and active upon contact

of the biological sample when it is added to the support. It is respectfully submitted that none of the cited references teach or suggest all of the elements of the claims, alone or in any combination. Accordingly, applicants request withdrawal of this ground of rejection.

*Rejection of claim 68 under 35 U.S.C. § 103 as being unpatentable over Deggerdal in view of Shieh or Harvey in view of Rudi.*

For the reasons discussed above, none of Deggerdal, Shieh, Harvey nor Rudi teach or suggest all of the elements of the base claim from which claim 68 depends (i.e. claim 63). Further, none of these references teach or suggest the recited eluting reagent of claim 68. The recited eluting reagent requires a pH of at least 10.0. The examiner argued that the Su reference teaches an elution buffer of 9.0 and argued that this was “about 10.5.” However, the claim has been amended to recite at least 10.0. 9.0 is clearly not at least 10.0. Accordingly, none of the cited references teach or suggest all of the elements of the claims, alone or in combination and accordingly, applicants request withdrawal of this ground of rejection.

*Rejection of claims 92-93 under 35 U.S.C. § 103 as being unpatentable over Deggerdal in view of Shieh or Harvey in view of Rudi and further in view of Arnold.*

For the reasons discussed above, it is respectfully submitted that Deggerdal, Shieh, Harvey and Rudi do not teach or suggest the recited elements of the base claim from which claims 92-93 depend (i.e. claim 63). Arnold does not cure these deficiencies as it does not teach each and every claim element. Namely, it does not teach or suggest that both the lysing reagent and the RNA digesting enzyme are dried before addition of the biological material. Further Arnold does not teach or suggest that the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer, and optionally a chelating agent. Accordingly, applicants request withdrawal of this ground of rejection.

*Rejection of claim 91 under 35 U.S.C. § 103 as being unpatentable over Deggerdal in view of Shieh in view of Rudi or Harvey in view of Hasebe.*

For the reasons discussed above, Deggerdal, Shieh, Harvey and Rudi do not teach or suggest all of the elements of the base claim from which claim 91 depends (i.e. claim 63). Hasebe does not cure these deficiencies as it does not teach each and every claim element. Namely, Hasebe does not teach or suggest that both the lysing reagent and the RNA digesting enzyme are dried before addition of the biological material. Further Hasebe does not teach or suggest that the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer, and optionally a chelating agent. Accordingly, applicants request withdrawal of this ground of rejection.

Rejection of claims 110-111 under 35 U.S.C. §103(a) as being unpatentable over Heath in view of Deggerdal in view of Shieh in view of Rudi or Harvey.

Claims 110 and 111 are now written in independent form. However, all the reasoning advanced *supra* regarding Deggerdal, Shieh, Harvey and Rudi are relevant here. To wit, these claims recite an isolation step that includes features that are now recited in claim 63 and these four references fail to teach or suggest the same. These features include the fact that the lysing reagent and RNA digesting enzyme are dried on the solid support when the biological material contacts the solid support as well as the fact that the lysing reagent consists essentially of a detergent, optionally water, optionally a buffer, and optionally a chelating agent. Heath does not cure these deficiencies as Heath does not teach either of these aspects of an isolating step.

There is simply no basis to conclude that a process of purifying DNA from white blood cells (claim 110) or from yeast cells (claim 111) would have been obvious from the proffered combination of references. Accordingly, applicants request withdrawal of this ground of rejection.

## **CONCLUSION**

Applicants believe that the claims are in condition for allowance and respectfully request such allowance. The Examiner is invited and encouraged to contact the undersigned at 202-508-3450 to discuss any matter in this application. Although it is believed that no fees are required for the filing of this paper, if any additional fees are

required, they may be charged to Deposit Account No. 50-4254, referencing Attorney Docket No. 2902162-015000.

Respectfully submitted,

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